

## IMPLEMENTATION OF A PERSONNEL RELIABILITY PROGRAM AS A FACILITATOR OF BIOSAFETY AND BIOSECURITY CULTURE IN BSL-3 AND BSL-4 LABORATORIES

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In late 2010, the National Biodefense Analysis and Countermeasures Center (NBACC) implemented a Personnel Reliability Program (PRP) with the goal of enabling active participation by its staff to drive and improve the biosafety and biosecurity culture at the organization. A philosophical keystone for accomplishment of NBACC's scientific mission is simultaneous excellence in operations and outreach. Its personnel reliability program builds on this approach to: (1) enable and support a culture of responsibility based on human performance principles, (2) maintain compliance with regulations, and (3) address the risk associated with the insider threat. Recently, the Code of Federal Regulations (CFR) governing use and possession of biological select agents and toxins (BSAT) was amended to require a pre-access suitability assessment and ongoing evaluation for staff accessing Tier 1 BSAT. These 2 new requirements are in addition to the already required Federal Bureau of Investigation (FBI) Security Risk Assessment (SRA). Two years prior to the release of these guidelines, NBACC developed its PRP to supplement the SRA requirement as a means to empower personnel and foster an operational environment where any and all work with BSAT is conducted in a safe, secure, and reliable manner.

**B**IOLOGICAL AGENTS WITH THE POTENTIAL to pose a severe threat to public health and safety have been designated as biological select agents and toxins (BSAT) by the US Department of Health and Human Services.<sup>1</sup> Biocontainment facilities that plan to possess or work with BSAT are required to register with the Federal Select Agent Program (FSAP). In addition, the Code of Federal Regulations (CFR) requires that personnel with access to BSAT must successfully undergo a Security Risk Assessment (SRA) by the Federal Bureau of Investigation (FBI) and be approved by either the Centers for Disease Control and Prevention (CDC)<sup>2</sup> Select Agent Program or the US Department of Agriculture (USDA) Animal and Plant Health

Inspection Services (APHIS) Agricultural Select Agent Program (7 CFR 331 and 9 CFR 121).<sup>3</sup> Recently, the CFRs governing use and possession of BSAT were amended to require a pre-access suitability assessment with ongoing evaluation for people accessing Tier 1 BSAT. Prior to these guidelines, the former legally required process focused largely on conducting background checks and assessing an individual's past activities.

In 2010, the National Biodefense Analysis and Countermeasures Center (NBACC) recognized the need to develop and implement a Personnel Reliability Program (PRP) in support of biosecurity to create an operational environment where work with BSAT would be conducted

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in a safe, secure, and reliable manner. In addition to being a risk-based assessment tool, the design of the NBACC PRP was driven by the goal of furthering leadership efforts to instill and promote an operating culture of reporting and learning that has been encouraged through the recognition of Human Performance Principles,<sup>4</sup> a Lessons Learned Program,<sup>5</sup> and institution-wide self- and independent-assessment procedures. It has been recognized that both reporting and learning promote a culture of responsibility,<sup>6</sup> which in turn leads to a more reliable organization.<sup>7</sup>

To establish a screening and monitoring tool for reliability that emphasized staff empowerment, NBACC researched various models, guidance documents, and regulations in developing its PRP. Among those reviewed were the Army Regulation 50-1 Biological Surety,<sup>8</sup> the Nuclear Regulatory Commission (NRC) Trustworthiness and Reliability Requirements (Order EA-05-090 and Order EA-07-305), NRC Responsible Research,<sup>9</sup> the National Science Advisory Board for Biosecurity (NSABB) Guidelines for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility,<sup>6</sup> and the National Institutes of Health (NIH) Behavioral Health Screening Program.<sup>10</sup> The resulting PRP is one that: (1) serves as a tool for management to make risk-based assessment decisions to ensure that people with access to BSAT materials meet high standards of reliability; (2) maintains a safe and secure work environment for all employees; (3) fosters a culture in which staff members watch out for each other and take responsibility for their own performance and that of others; and (4) provides a safe reporting mechanism for staff to self-report and peer-report, relaying any concerns about other staff members. In addition, the NBACC PRP fulfills the FSAP requirement for a pre-access suitability assessment and an ongoing evaluation for people with access to Tier 1 BSAT.

## PREMISE OF THE PERSONNEL RELIABILITY PROGRAM

NBACC leadership began the process of developing a PRP based on a few principles that embodied their operating culture, such as realizing that people do make mistakes and that the organization can have a role in influencing if and when those mistakes are reported (ie, near misses and nonactionable situations that become learning events). The same can be observed with respect to how a positive environment can influence whether an individual will self-report personal matters that may interfere with concentration and focus thus impairing safe and secure work practices. This premise is vital in creating a responsible culture in which distinctions are made between honest mistakes and intentional deviations from acceptable practices and in which people are accepted based on their intentions and not on circumstances. Operating in a reporting and learning environment creates an “atmosphere of trust”<sup>8</sup>

by promoting the free flow of information, and this, in turn, influences self-reporting by staff. These cultural principles enable staff members to understand the difference between acceptable and unacceptable behaviors based on consistent and clear standards that are communicated by leadership and, in turn, administered by the PRP.

Reviews were conducted of existing reliability programs to understand process as well as means and measures that would bolster the NBACC institutional priorities.<sup>11</sup> It was determined that a PRP should enhance existing security measures to avert the insider threat; for a program to be successful, it should be embraced by the staff as such a tool. Staff should be able to use the program as they need, which inevitably leads to a culture of responsibility. Thus, a PRP cannot operate as a purely punitive program, and it should provide assurance that personnel will not be unduly penalized should they suffer illnesses or personal issues that occur because they are human. The program should enable personnel to become their own advocates and allow them to freely engage in conversation with PRP officials without fear of retribution or of being judged on their personal choices, as opposed to their reliability. Therefore, it provides for respect for individuality, while also ensuring that any perceived harmless behaviors are not actually menacing to safe and secure operations. For example, personnel should not be judged on day-to-day personality eccentricities, sexual orientation, hobbies, or otherwise innocuous personality traits, but rather on whether they can be blackmailed, coerced, or otherwise manipulated.<sup>12</sup> Invoking such ideals establishes a nonpunitive environment for reporting. Maintaining these principles and practices ensures a holistic evaluation of the person, as well as a compassionate program in which any investigation or disciplinary action is conducted with respect, in a consistent, objective, and confidential manner that is transparent to the staff member.

In addition, leadership embraced the importance of providing support mechanisms, including an occupational health professional and an employee assistance program (EAP), at no expense to the employee, as avenues for staff to proactively obtain help to deal with personal matters and concerns. The leadership wanted to send a clear message: “We put people and safety first. It’s okay at NBACC to seek help, recognize a coworker needs intervention, or opt out of laboratory work for a period of time without significant impact to your position or job.” Leadership also wanted it recognized that if a staff member was certified in the PRP, that certification implied attributes of reliability, including:

- Integrity;
- Trustworthiness;
- Responsibility;
- Teamwork;
- Safe work practices;
- Secure work practices;
- Community; and
- Respect.

An individual's certification in the NBACC PRP establishes equal expectations by the organization that the individual and his or her peers are all held to the same high standards, and it is expected that co-workers look out for one another by monitoring the safe and secure work practices used by everyone. This responsibility holds the staff member accountable to the PRP for failure to report any observed safety and security concerns.

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## STAFF ROLES AND RESPONSIBILITIES

Approximately 100 workers at NBACC are certified in the PRP. Requirements for enrollment include any personnel with routine access to BSAT; an authorization to escort visitors to areas containing BSAT; the ability to control direct access to BSAT (eg, grant access cards, PINs, keys, combinations, biometric codes, or any other mechanism providing access to BSAT); and the CDC-defined positions of responsible official (RO) or alternate responsible official (ARO). Program management and reporting are rigorous and require coordination and communication across several areas. The following positions were important in implementing the program:

- *Certifying official (CO)*: evaluates reliability of individuals participating in the program;
- *Laboratory director (LD)*: overall implementation responsibility, appoints certifying officials, appoints occupational health professional, reviews disqualifications if requested by employee;
- *Occupational health professional*: reviews healthcare services, medical reports, and medical histories; conducts clinical evaluations; reports relevant information affecting reliability to the certifying official;
- *Human resources representative*: reviews personnel files for any relevant information that could affect reliability and reports that information to the certifying official;
- *Security representative*: reviews security files; ensures applicable background checks have been completed; reports information that could affect reliability to the certifying official;
- *Responsible official/biosecurity manager*: liaison and external support to the biosecurity mission; reports back to CDC and/or APHIS when applicable;
- *Process owner*: serves as the subject matter expert for the program with responsibility for implementation and ongoing monitoring of its effectiveness; and
- *Management system owner*: acts as the management authority for the program with responsibility for securing the resources necessary for implementation and ensuring that the process receives appropriate technical review.

NBACC has chosen not to incorporate the responsible official or the alternate responsible official in the PRP process

for determining reliability. The responsible official and the alternate responsible official directly receives PRP reports on any actions that will affect access. The CDC Guidance for Suitability Assessments (7 CFR Part 331, 9 CFR Part 121, 43 CFR Part 73) specifies a role for a reviewer (REV) to have oversight of the program. NBACC has designated 2 of the 3 certifying officials for oversight of the PRP as process owner and management system owner. Segregation of these duties ensures oversight without compromising the confidentiality of information held by the PRP.

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## ENROLLMENT IN THE PROGRAM

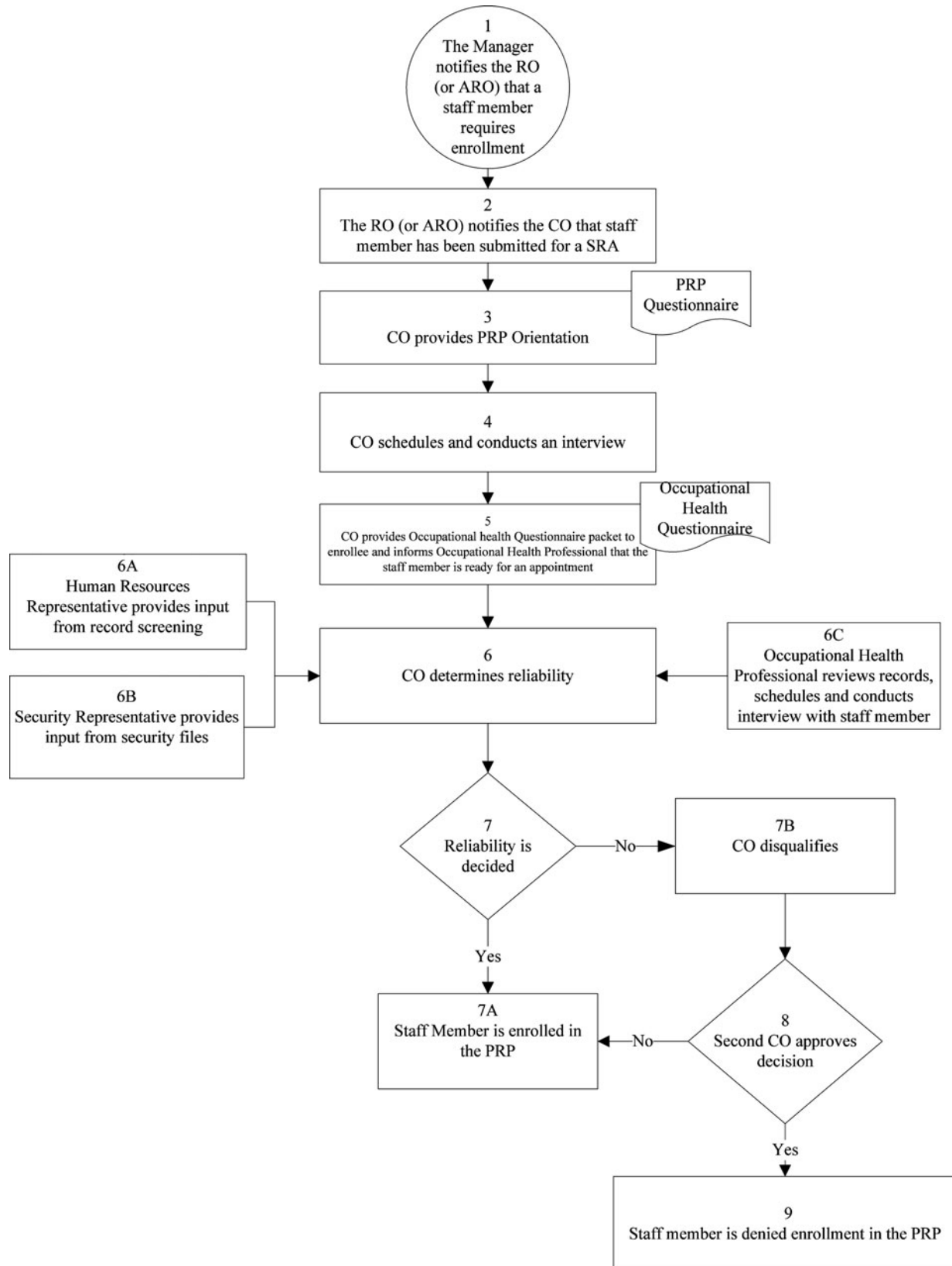
Enrollment in the PRP is orchestrated across several components of the organization. The information collected is handled in strict confidence with access given only to those staff appointed as certifying officials. Figure 1 summarizes the enrollment process. It should be noted that access to BSAT has additional requirements that are managed and maintained separate from the PRP and that may include requirements for medical surveillance, technical/procedural training, mentorships, biosafety training, biosecurity training, and quality training.

When necessary, a manager notifies the responsible official that a staff member needs access to BSAT. The responsible official requests that the certifying official provide the PRP training overview to acquaint the individual with the program mechanics and answer any questions about the program so the enrollee is at ease with the process and understands what to expect throughout enrollment and certification. At the conclusion of the PRP training, the staff member receives a copy of the PRP interview questionnaire. The certifying official then schedules an appointment with the staff member for the initial interview, which includes a review of the enrollee's answers to the questionnaire. This one-on-one interface allows for clarification of any responses, and it allows the certifying official to collect any mitigating details for adverse information reported.

The occupational health professional will then schedule an appointment with the staff member to complete a drug screen urinalysis and evaluate any medically related information, such as depression, drug use, or chronic illness. The occupational health professional will report any medical risks that need to be factored into the reliability determination and any applicable medical recommendations to the certifying official.

Concurrently with the occupational health review, the human resources (HR) representative will review the personnel record, which includes the staff member's resume or curriculum vitae, a credit report with bankruptcy check, a criminal background check, a sex offender registry check, and confirmation of education and previous employment. The HR representative will report any relevant information to the certifying official. The security operations representative confirms to the certifying official that the staff member has completed all background checks required for the position.

Figure 1. Enrollment in the Personnel Reliability Program



The certifying official reviews the input from the HR representative, the occupational health professional, and the security operations representative. The PRP enrollment process is often initiated in parallel with the SRA. Because certification into the PRP is contingent on receipt of the SRA, the certifying official confirms with the responsible official that the staff member has received a favorable SRA.

The information gathered from all entities and the certifying official's initial interview with the staff member are used to formulate the decision of reliability. This decision is based on reliability of past performance and the candor of the staff member in disclosing factors that could potentially influence reliability. The information is used by the certifying official as an overall assessment of the individual to predict whether he or she will meet the requirements for safe and secure operations. If these reliability standards have been met, the certifying official will certify the staff member into the PRP. If reliability cannot be established, the certifying official will proceed with the process for disqualification (see below). Unescorted access to areas with BSAT is granted only to individuals certified in the PRP.

Being certified in PRP is an ongoing process. The certifying official monitors certified staff members throughout the year through the following activities:

- Self-reporting by staff members to the certifying official or, in the case of medical matters, to the occupational health professional, of medical conditions, prescription and over-the-counter medications used, alcohol abuse, legal actions, public record court actions (eg, separation, divorce, lawsuit), financial problems or concerns, or any other activity that may influence the staff member's day-to-day reliability;
- Peer and manager/supervisor observation and reporting of behaviors or events affecting an individual's day-to-day reliability;
- Evaluation and medical treatment by the occupational health professional;
- Random drug testing; and
- An annual meeting with the certifying official.

It should be noted that there is no formal reporting process. An informal reporting environment has been in-

tionally fostered to promote employee and manager reporting compliance. Reports to the PRP can be generated through any means (eg, phone conversations, e-mail, face-to-face meetings). In our experience, most instances of reporting have been through face-to-face meetings with the certifying official.

## MEDICAL AND BEHAVIORAL COMPONENTS

The occupational health professional is central to medical management at NBACC, not only with regard to PRP but for all aspects of occupational health, including fitness for duty, review of personnel risk assessments, comprehensive physical exams, titer tests/immunizations, respirator clearance, hearing/vision tests, health questionnaires, animal handler questionnaires, and the like. As such, the occupational health professional is well known and regarded among staff. As staff provides the most personal types of information to the occupational health professional, a bond of trust that privacy is maintained and respected becomes established. We have found that having one person serve as the occupational health professional, who provides support for all medical management, is immensely beneficial to reinforcing a trusting relationship for the staff certified in the PRP.

NBACC leadership specified that the appointment of the occupational health professional was contingent on credentialing that would meet the requirements outlined by the Army Biosurety Program (AR 50-1). This decision was made to define the occupational health professional's responsibilities as providing recommendations to the certifying official for consideration, as opposed to exercising actions through the PRP. This distinction gives the decision-making authority to the certifying official and allows the occupational health professional to be a resource to both the individual staff member and the overall PRP. Additionally, the occupational health professional participates in continuing education that relates to both reliability concerns and topics relevant to the nature of work conducted in a biocontainment facility. An example of these continuing education efforts are the regular video teleconferences sponsored by the US Army Medical Command on a variety of topics including diagnosis, evaluation, and treatment of laboratory-acquired anthrax; office screening for

Figure 2. Training and Continuing Education

- US Army Medical Command (MEDCOM) Biological Surety Medical Support Course
- Annual CDC-sponsored Occupational Health Colloquiums for Preventing and Treating Biological Exposures
- US Army Medical Research Institute of Chemical Defense/US Army Medical Research Institute of Infectious Diseases training course for Medical Management of Chemical and Biological Casualties (MCBC)



psychological and behavioral health issues; occupational asthma; respiratory clearance; and case studies on substance abuse and substance dependency evaluations. Additional training and continuing education efforts are listed in Figure 2.

The PRP medical evaluation augments the enrollment process for drug and alcohol concerns, as well as mental health matters. Additional evaluations, if indicated, are performed in the initial interview and/or during the medical review for PRP or, if necessary, during the ongoing evaluation; these include the Beck Anxiety Inventory, the Beck Depression Scale, CAGE (alcohol screen), and DANYA Drug and Alcohol Screen.

In order to have cohesive communication between the certifying official and the occupational health professional, enrolling staff members are asked to sign a Privacy Act of 1974<sup>13</sup> waiver, which releases the certifying official to talk to the occupational health professional and the HR and security representatives. The enrolling staff member is also asked to sign a Health Insurance Portability and Accountability Act (HIPAA)<sup>14</sup> waiver, releasing the occupational health professional to disclose to the certifying official any medical matters that could affect reliability. If a staff member does not sign both waivers, the enrollment process is immediately terminated.

## FACTORS CONSIDERED IN RELIABILITY DECISIONS

Certification in the NBACC PRP means that the following reliability factors have been considered and evaluated for the staff member:

- Mental alertness;
- Mental and emotional stability;
- Trustworthiness;
- Freedom from unstable medical conditions;
- Dependability in accepting responsibilities;
- Effective performance;
- Flexibility in adjusting to changes;
- Good social adjustment;
- Ability to exercise sound judgment in meeting adverse or emergency situations;
- Freedom from drug/alcohol abuse or dependence;
- Compliant with requirements; and
- Positive attitude toward PRP.

Evaluation of the factors listed above occur directly and indirectly through the following activities: (1) during the enrollment interview by the certifying official in which an extensive review of the PRP questionnaire responses are discussed with the staff member; (2) through the feedback received from the HR and security representatives; and (3) through the interview and applicable assessment tools conducted by the occupational health professional. The compilation of these evaluative processes allows the certifying official

to judge whether all factors have been favorably assessed and if the staff member is eligible for certification into the PRP.

The following factors would preclude a reliability decision and are considered to be disqualifying:

- Diagnosis of drug or alcohol dependence;
- Drug abuse in the 5 years prior to the initial PRP interview;
- Trafficking, cultivating, processing, or manufacturing illegal or controlled drugs; and
- Drug or substance abuse while enrolled in PRP.

Additionally, the following factors would require further evaluation, on a case-by-case basis:

- Inability to meet safety requirements;
- Poor attitude or lack of motivation;
- Aggressiveness or threatening behavior; and
- Concealment of information from the certifying official or false information.

## A CULTURE OF RESPONSIBILITY

Depending on individual circumstances, the certifying official has the authority to implement any of the following actions: restriction, suspension, or disqualification.

### *Restriction*

Because safety and security are of paramount importance at NBACC, conditions that could affect a staff member's working in a safe and a secure manner are managed through PRP restriction. Restriction is an administrative action to temporarily remove an individual's access to BSAT areas, but it does not affect the staff member's PRP status. The certifying official may issue a restriction based on input from the occupational health professional for medical concerns or at the request of the staff member. In the case of a self-request, the staff member contacts a certifying official to discuss the purpose of the request, and a generic restriction notice is then generated (with no details regarding the nature of the restriction, except for an approximate return date) and is disseminated to management and the security representative. Access to BSAT is removed for the duration of the restriction to protect the employee from being compelled by any peer or management personnel to perform activities involving BSAT.

Allowing a staff member to voluntarily opt out of laboratory activities when his or her ability to operate in a safe and secure manner is compromised empowers staff members to manage and be responsible for their own safe and secure operations. This responsibility to ensure their own safe and secure operations also helps promote a sense of community with, and responsibility for, fellow staff members. If another staff member exhibits questionable operational behavior, peer reporting of this information to

the certifying official supports a culture of responsibility. Restriction requests are honored without threat of punishment, thus eliminating any feelings by staff members that they must conceal problems for fear of losing PRP status. The NBACC PRP views voluntary disclosure of personal difficulties and challenges as a sign of integrity, something that is greatly valued and respected in its staff. These reports are always received with compassion and confidentiality by the certifying official.

Management is trained to avoid questioning staff members about the nature or duration of a restriction notification. In the event that inquiries are raised, management has been instructed that such inquiries should be redirected to the certifying official. If a manager directs any questions to the staff member, the staff member knows to bring this to the attention of the certifying official so that the certifying official may intervene with that manager. Retribution against an employee is not tolerated. Laboratory absences because of restriction are managed in a similar manner as temporary assignments (eg, when the laboratory spaces are unavailable for work due to maintenance) or a staff member is absent because of illness or vacation.

An example of an employee request for restriction might be having a new baby in the family and not being able to get adequate rest. Rather than work with BSAT while fatigued, with compromised concentration, an employee can request a PRP restriction from the certifying official. A medical reason for a restriction could involve a staff member's taking a new medication that makes him drowsy or requires an adjustment time period. In this case, he would discuss the situation with the occupational health professional, who would then recommend restriction to the certifying official. An example of a restriction for emotional reasons would be due to bereavement over the loss of a family member, including cherished pets; while people may feel embarrassed to discuss grieving for a pet, the loss can still affect their ability to concentrate and work safely. In cases of bereavement, staff members could be referred to the employee assistance program for counseling.

## *Suspension*

Suspension from the PRP is the action the certifying official uses to remove an individual's access to BSAT areas as a result of a staff member's reliability being called into question. The certifying official will inform the staff member of the allegations that have been raised and, depending on the nature of the issue, may ask the staff member to help facilitate resolution of the matter. A notification of suspension will be generated and sent to management, the responsible official, and security operations to terminate the staff member's access to BSAT. A description of the findings that prompted the suspension and any information generated through investigation and evaluation of the matter will be maintained in the staff member's PRP file. Once the issue eliciting the suspension has been resolved, a notification of reinstatement will be

provided to management, the responsible official, and security operations to restore access to BSAT areas.

A notification of suspension may be issued when a staff member receives notice to submit for a random urine drug screen and he or she does not comply by the end of that business day. If the staff member simply forgot and self-reports to the certifying official, in consultation with the occupational health professional, that staff member may be asked to report for the test first thing the next morning, with no suspension issue. However, if the staff member does not self-report to the certifying official or comply by the next morning, the certifying official will issue a notification of suspension with immediate removal of access to BSAT areas.

## *Disqualification*

In the event a suspension cannot be resolved or reliability cannot be initially determined, the certifying official will begin the process for disqualification from the PRP. A notification of disqualification will be generated that includes a description of the findings that prompted the action. This notification will be sent to a second certifying official for review of the findings and any relevant information the second certifying official deems necessary. The purpose of this review is to establish concurrence to disqualify the staff member from the PRP, and, upon concurrence of the disqualification, the staff member will receive the notification of disqualification. Disqualification notifications are provided to the laboratory director, management, the responsible official, the occupational health professional, and security operations. In turn, each individual discipline will then make any necessary notifications (eg, the responsible official will report to CDC and/or APHIS). If a staff member believes the disqualification has been administered unfairly, he or she may request a formal review by the laboratory director, in writing, stating the reason(s) for disagreement. If the laboratory director overturns the decision of disqualification, the staff member will be returned to the certifying official for reinstatement in the PRP. Should a disqualification be overturned by the laboratory director, such a decision will be assessed to determine whether there is a need for a corrective action to the PRP process. Furthermore, if a corrective action is administered, it will also be subsequently assessed to determine its effectiveness. This continual improvement cycle invokes the nature of a learning culture that NBACC promotes in all of its processes.

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## CONCLUSION

NBACC continually measures various aspects of the PRP to ensure that it is fulfilling its safety and security mandates to both leadership and staff. Examples of these metrics include: the number of reports received by the certifying official and occupational health professional; the number of actions

(restrictions, suspension, disqualifications) administered through the program; and the number of direct interactions between the certifying official and staff members.

During a typical month, the following number of PRP reports are generated: approximately 12 medical reports to the occupational health professional that do not require a restriction from access; approximately 3 nonmedical reports to the certifying official that require no PRP action; approximately 4 nonmedical reports that require follow up with the certifying official but result in no PRP action; and approximately 12 restrictions, which are either medical or personal in nature. At the time of its initial deployment, the PRP tracked similar metrics to create a baseline to measure staff use of the program.

NBACC has created a dynamic PRP that adapts and changes to maximize staff compliance while maintaining consistency of principles and expectations. During the initial year of deployment, more than 100 staff members were certified in the PRP. Staff members have been and continue to be encouraged to provide feedback on the program and its processes through direct communication and anonymous surveys deployed by NBACC's quality assurance department. Staff members have been forthright with feedback, and this feedback has been used to improve the program. Examples of changes suggested by staff included the addition of self-expiring restrictions managed by the staff member and a certifying official opt out, in which 1 of the 3 certifying officials is restricted from accessing an employee's PRP data at the request of that employee. The overall level of feedback from staff, and the nature of suggestions received, provides strong support that the PRP is functioning as intended to drive and improve the biosafety and biosecurity culture at NBACC.

By continuing to employ these assessments and tracking practices, those who work with the PRP will continue to learn and adapt the program to the organization to best meet the changing needs of management and support staff compliance, while maintaining the integrity of the program's purpose to provide safe and secure operations at NBACC.

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